

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA261-16-AP-8855, 640-17-2-034-0018 HCV-HIV Viral Load Tests

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: Abbott Molecular

Manufacturer/Contractor POC & phone number: Lisa Koenig, 415-269-2911

Mfgr/Contractor Address: 1300 East Toughey Ave, Des Plaines, IL 60018

Dealer/Rep address/phone number/e-mail address: lisa.koenig@abbott.com

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network Contracting Office (NCO) 21

VA Palo Alto Health Care System

VISN 21

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

The VA Palo Alto Health Care System (VAPAHCS) has a need to purchase Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Viral Load Test Kits and supporting reagents and supplies for the VAPAHCS due to the upcoming expiration of their current order. This is an annual requirement for VAPAHCS. HCV and HIV viral load tests are performed on patients who test positive with respective HCV or HIV antibody screening tests. The molecular based viral load tests determine the amount or level of active virus in the patient's blood stream. The provider uses this test result to decide if the treatment drugs are effective in reducing the virus.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The VAPAHCS is requesting a sole source delivery order with Abbott Laboratories, Inc., Molecular Division for HCV and HIV Viral Load Tests with supporting reagents and supplies. This is a cost per test order. The following requested items are available on a Medical FSC 65 FSS NAC Contract No. V797D-40222 with Abbott Laboratories, Inc.

Item #	Description/Part Number*
1	HCV Amp Reagent Kit - 01N30-90
2	Sample Prep GPR Pack RNA - 04J70-024
3	Disposable Tips (DiTis) 1ML, 2,304 tips/case - 04J71-10
4	96 Deep Well Plates (32 plates per box) - 04J71-30
5	HIV-1 Amp Reagent Kit - 06L18-90

6	HIV-1 Control Kit - 06L18-80
7	HIV-Calibrator Kit - 01N30-70
8	HCV Calibrator Kit - 01N30-70
9	Disposable Tips (DiTis) 200 UI - 04J71-17
10	5 mL Reaction Vessels - 04J71-20
11	200 mL Reagent Vessel - 04J71-60
12	Optical Adhesive Covers - 04J71-75
13	96 Well Optical Reaction Plates - 04J71-70
14	m2000 Optical Calibration Kit - 04J71-93
15	Biohazard Bags, Orange - 04J71-45
16	m2000rt Bulb - 09K33-01 (<i>Open Market Item</i>)
17	Master Mix Tubes/Caps (150/Bx) - 04J71-80
18	Realtime HCV Control Kit - 01N30-80

(b) ESTIMATED DOLLAR VALUE: \$3,392,517.00

(c) REQUIRED DELIVERY DATE: 01/23/17 - 1/22/2022

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

The following salient characteristics included within the Abbot system are essential to the Government's requirement:

- Must accept a primary patient tube without the purchase of an additional instrument.
- Shall use external calibrators.
- Automation must have open mode for laboratory developed tests.
- Shall have the capability to run HCV genotype.

The Abbot system for HCV and HIV viral load testing meets all the requiring activity's minimum needs listed within the salient characteristics above. This requirement can only be met by one source based on market research results.

Based on above, only Abbott is capable of providing the supplies and services requested as the level of quality required because the supplies and services are unique or highly specialized IAW FAR 8.405-6(a)(1)(i)(B).

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

The fixed prices for supplies and services listed under FSS Contract V797D-40222 have been determined to be fair and reasonable by GSA. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing. The prices listed under FSS Contract V797D-40222 represent the best value (as defined in FAR 2.101) and results in the lowest overall cost alternative (considering pricing, special features, administrative costs, etc.) to meet the Government's needs

This request contains one open market item with an estimated total annual amount of \$675. Data other than certified cost or pricing data will be requested for these items to ensure that VA is receiving pricing consistent with pricing Abbott provides to their best Commercial and Federal customers.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

A Sources Sought Notice (RFQ1048427) was posted via GSA eBuy on 11/02/2016 and closed on 11/10/2016. The notice included the salient characteristics and statement of work of the requirement. Any firm that believed it could provide the supply items listed were encouraged to submit written notification to the Contracting Specialist with requested information for consideration before the close of the Sources Sought Notice. One response was received from Abbott Laboratories, Inc. indicating it can meet VA's requirement.

A Sources Sought Notice (VA261-17-N-0060) was also posted via FBO on 11/02/2016 and closed on 11/10/2016. A copy of the FBO Sources Sought notice was forwarded to certified SDVOSB and VOSB vendors who are listed under the NAICS 334516 and key phrase "HIV HCV Viral Load Test." One SDVOSB vendor expressed interest, but without the submission of the information requested outlined in the sources sought notice, there is a reasonable expectation that it is unable to provide any desired products that meet or exceed the statement of work and salient characteristics listed.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

N/A

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

VA will continue to monitor the commercial marketplace to determine if other sources are capable of providing HCV and HIV Viral Load Tests with supporting reagents and supplies that meet the needs of the VAPAHCS. Systems need to be validated by the Government to determine if they actually can perform the required tests. This validation may occur during the Government's market research phase. Once other sources enter the market place and are validated by the Government, future procurements may be competitive.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This*

signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)

_____ SIGNATURE		12/6/2016 _____ DATE
<u>Sang Gross</u> Name	<u>Laboratory Manager</u> TITLE	<u>Pathology</u> SERVICE LINE/SECTION
<u>VA Palo Alto Health Care system (VAPAHCS)</u> FACILITY		

(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: OFOC SOP](#):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____ Susan Battjer Contracting Officer, NCO 21	_____ DATE
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b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____ Samuel M. Harbin Director of Contracting, NCO 21	14 Dec 2016 _____ Date
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c. VHA HCA REVIEW AND APPROVAL (over \$650,000 to \$12.5 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

_____ Delia A. Adams, MBA, CPCM Director, SAO West Head of Contracting Activity	_____ DATE
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